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**VIA CM/ECF**

Jarrett B. Perlow
Clerk of the Court
U.S. Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

Re: *Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.*, Nos. 22-2153 & 23-1952

Dear Mr. Perlow:

Pursuant to Rule 28(j), Appellants respectfully advise that on November 1, the district court in *Norwich Pharmaceuticals, Inc. v. Becerra*, No. 1:23-cv-01611 (D.D.C.), entered summary judgment in favor of FDA and Salix Pharmaceuticals, Inc. The attached Memorandum Opinion explains its reasoning.

Norwich alleged that FDA acted arbitrarily and capriciously by not granting final approval to its ANDA. FDA interpreted the Delaware judgment below to "preclude the agency—without limitation—from granting final approval to Norwich's ANDA before October 2, 2029." Dkt. 65 at 28. The D.C. district court held that FDA's reading of the judgment "was not only reasonable but was by far the better reading." *Id.*

Although the merits of the Delaware judgment were not at issue, Norwich urged the D.C. district court to interpret the judgment in light of the "presumption of regularity" and thus consider "the FDA's governing regulations and the policy favoring the prompt approval of non-infringing generic [drugs]." *Id.* at 32.

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In rejecting these arguments, the decision touches on issues involved in Norwich's cross-appeal. As Salix urges this Court, Resp. & Reply Br. 45-50, the D.C. district court found "instructive" this Court's decision in *Ferring B.V. v. Watson Laboratories, Inc.-Fla.*, 764 F.3d 1382 (Fed. Cir. 2014). Dkt. 65 at 35. It also looked to *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, No. 14-1119, 2019 WL 3574249 (D. Del. Aug. 6, 2019), and *Allergan, Inc. v. Sandoz Inc.*, No. 09-97, 2013 WL 6253669 (E.D. Tex. Dec. 3, 2013). *Compare* Dkt. 65 at 36-37, *with* Resp. & Reply Br. 61-62.

According to the D.C. district court, these decisions comport with "[c]ommon sense," which "at least arguably suggests that this is not a one-size-fits all question, in which district courts are empowered only to specify an approval date with respect to the infringing methods-of-use and must, invariably, carve out from their judgments any future, amended ANDAs that are limited in scope to those methods-of-use that were not found to be infringing at trial." Dkt. 65 at 37. Such an inflexible approach might "unfairly prejudice patent holders." *Id.*; *see* Resp. & Reply Br. 45-52, 61-62.

Respectfully submitted,

*/s/ William R. Peterson*
William R. Peterson
*Counsel for Appellants*

Enclosure

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

NORWICH PHARMACEUTICALS, INC.,

*Plaintiff*,

v.

XAVIER BECERRA,
*Secretary of Health and Human Services*,
*et al.*,

*Defendants*.

Civil Action No. 23-1611 (RDM)

**MEMORANDUM OPINION**

Battles over the entry of generic drugs to market are often hard fought, particularly in cases involving brand-named drugs with annual sales that substantially exceed $1 billion. *See* Dkt. 1 at 11 (Compl. ¶ 41). This is a case in point.

Defendant-Intervenor Salix Pharmaceuticals, Inc. ("Salix") currently markets rifaximin (under the brand name Xifaxan) for the treatment of irritable bowel syndrome with diarrhea ("IBS-D") and the reduction of risk of hepatic encephalopathy ("HE") recurrence in adults. Dkt. 1 at 3, 11 (Compl. ¶¶ 10, 39); Dkt. 12-1 at 3. Plaintiff Norwich Pharmaceuticals, Inc. ("Norwich") wants to market a generic version of the drug. Dkt. 1 at 24 (Compl.). But before it may do so, it must obtain final Food and Drug Administration ("FDA") approval of its Abbreviated New Drug Application ("ANDA") for the drug. *See* 21 U.S.C. § 355. Obtaining approval of an ANDA, however, requires more than evidence of bioequivalence, safe manufacturing procedures, and proper labeling. The generic drug applicant must also work its way through a maze rules that lie at the intersection of FDA regulation and the patent laws.

Here, that maze began with the filing of Norwich's original ANDA, which identified twenty-three patents that, according to Salix, protected Xifaxan from competition. Dkt. 4-1 at 14. That filing constituted an act of patent infringement, leading Salix to initiate infringement litigation against Norwich. *Id.* at 17. Over the course of the litigation, the field of dispute narrowed, ultimately leading to a district court decision that invalidated two drug substance patents and the two method-of-use patents covering the IBS-D indication. Dkt. 4-4 at 47. But the district court found that Salix's three HE method-of-use patents were valid and infringed. *Id.* Based on that finding, the court entered an order directing "that the effective date of any final approval order of the [FDA] of Norwich's ANDA . . . is to be the date not earlier than the expiration of the" HE method-of-use patents—that is, October 2, 2029. Dkt. 4-5 at 3.

That, however, was not the end of the road for Norwich. In light of the district court's decision, it returned to the FDA and filed an amended ANDA, which omitted the HE indication from its proposed label, and it filed a motion under Federal Rule of Civil Procedure ("Rule") 60(b) in the district court seeking to modify the judgment to permit the FDA to approve the amended ANDA without delay. Dkt. 4-1 at 18–19. The district court denied that motion, Dkt. 51 at 113–16, and Norwich appealed the scope of the district court's final judgment to the Federal Circuit. Dkt. 4-10 at 2. (Salix, for its part, cross-appealed the district court's invalidity findings.) The FDA, then, tentatively approved Norwich's ANDA, but it declined to grant final approval (that is, the approval necessary to go to market) before October 2, 2029, in compliance with the agency's reading of the district court's final judgment. Dkt. 51 at 119, 121.

That brings us to this case, in which Norwich challenges the FDA's decision only tentatively—and not finally—to approve Norwich's amended ANDA. Dkt. 1 at 23–24 (Compl. ¶¶ 95–103). Invoking the Administrative Procedure Act ("APA"), Norwich maintains that the

FDA's "grant of tentative rather than final approval of Norwich's [a]mended ANDA is arbitrary, capricious, and contrary to law," *id.* at 24, and it seeks injunctive and declaratory relief directing the FDA immediately to approve Norwich's amended ANDA, *id.*, so that the drug can go to market. In Norwich's view, the FDA misread the district court's order and, instead, should have read it to apply only to the company's original ANDA, which included the HE indication. On the same day that Norwich filed suit, it moved for a preliminary injunction. Dkt. 4. The FDA and Salix oppose that motion; the FDA has cross-moved for summary judgment, Dkt. 37; and Salix has both cross-moved for summary judgment and, in the alternative, moved to dismiss, Dkt. 54. At the parties' request, the Court consolidated the hearing on Norwich's motion for a preliminary injunction with proceedings on the merits pursuant to Rule 65(a).

For the reasons explained below, the Court will **DENY** Norwich's motion for a preliminary injunction and will **GRANT** the FDA and Salix's cross-motions for summary judgment.

## I. BACKGROUND

### A. Statutory Background

To obtain approval to market a new drug, the manufacturer must submit a new drug application ("NDA") to the FDA demonstrating, among other things, that the new drug is safe and effective. 21 U.S.C. § 355(b)(1). The NDA must also include "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." *Id.*; *see Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys*, Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008). This listing can include patents that "protect[] the drug compound itself" and those that "gives the [drug] manufacturer exclusive rights over a particular method of using

the drug." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Once the NDA is approved, the drug becomes a "listed drug" and all associated patents are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" or, as it is commonly known due to its orange cover, the "Orange Book." *See Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 301 (D.D.C. 2012).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984), popularly known as the "Hatch–Waxman Act." The Hatch-Waxman Act aims to strike "a balance between two competing policy interests: (1) inducing pioneering research and [the] development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). To that end, the Hatch-Waxman Act streamlined the process for bringing generic versions of previously approved drugs to market by creating the abbreviated new drug application—or ANDA—process, which permits the generic manufacturer to "piggyback[ ] on the original manufacturer's evidence of safety and efficacy," *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008), thereby avoiding the "need [to] conduct its own" costly clinical trials, *Mylan Lab'ys, Inc. v. Thompson*, 389 F.3d 1272, 1275 (D.C. Cir. 2004). To obtain FDA approval for a generic drug, the ANDA must demonstrate, among other things, that the generic version of the drug is "bioequivalent" to the listed drug and, at least in the ordinary course, that the labeling for the generic version is "the same as the labeling approved for the listed drug." 21 U.S.C. §355(j)(2)(A). As explained further below, however, the proposed ANDA labeling may—at times—carve out certain methods of use to avoid patent infringement. *See Caraco Pharm. Lab'ys*, 566 U.S. at 406.

Of particular relevance here, the ANDA must also contain "one of four certifications addressing each Orange-Book-listed patent associated with the listed drug." *Caraco Pharm. Lab'ys.*, 527 F.3d at 1282. For "each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval," the ANDA must contain a certification:

> (I) that [the required] patent information has not been filed [with the FDA];
>
> (II) that such patent has expired;
>
> (III) of the date on which such patent will expire; or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). "This certification is significant, in that it determines the date on which approval of an ANDA . . . can be made effective, and hence the date on which commercial marketing may commence." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990). If the applicant makes the first or second certification in its ANDA, "approval can be made effective immediately." *Id.* (citing § 355(c)(3)(A), 355(j)(4)(B)(i)). If the applicant makes the third certification, "approval of the application can be made effective as of the date the patent expires." *Id.* (citing § 355(c)(3)(B), 355(j)(4)(B)(ii). If, however, the applicant relies on the fourth certification—a so-called "Paragraph IV certification"—then a process to adjudicate a potential patent dispute is triggered and the outcome of that dispute will determine the effective date of the ANDA. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) ("In essence, applicants use paragraph IV certifications to challenge the validity of brand-name manufacturers' patents.").

As an alternative to a Paragraph IV certification, a drug company seeking approval for a generic drug may include a "section viii statement, which asserts that the generic manufacturer

will market the drug for one or more methods of use not covered by [the listed] patents." *Caraco Pharm. Lab'ys*, 566 U.S. at 406 (citing 21 U.S.C. § 355(j)(2)(A)(viii)). "For example, if a brand-name manufacturer's patent covers a drug's use for treating depression, and the ANDA applicant seeks approval to use the drug to treat any other condition, then a section viii statement would be appropriate." *Purepac Pharm.*, 354 F.3d at 880. In short, "applicants use [P]aragraph IV certifications to challenge the validity of admittedly applicable patents, they use section viii statements to assert that patents do not apply." *Id.* "A section viii statement is typically used when the [listed] patent on the drug compound has expired and [the manufacturer] holds patents on only some [but not all] approved methods of using the drug." *Caraco Pharm. Lab'ys*, 566 U.S. at 406. Along with the section viii statement, the ANDA must also include a proposed label for the generic drug that "carves out" from the listed drug's approved label the still-patented methods of use. *Id.* (citing 21 CFR § 314.94(a)(8)(iv)). As noted above, "[t]he FDA may approve such a modified label as an exception to the usual rule that a generic drug must bear the same label as the brand-name product." *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G)); *Purepac Pharm.*, 354 F.3d at 880 ("The FDA has long required that for every patent ANDA applicants use either a paragraph IV certification or a section viii statement—they may not use both. As the FDA puts it, 'either the applicant is seeking approval for the use claimed in the patent, or it is not.'" (quoting *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 77 (D.D.C. 2003))).

If the generic applicant does not pursue the section-viii-statement route and instead relies on a Paragraph IV certification in its ANDA, it "must provide [a] notice of [its] Paragraph IV certification to both the patent owner and the NDA holder," which explains "the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed." *Caraco*

*Pharm. Lab'ys*, 527 F.3d at 1283 (quoting 21 U.S.C. § 355(j)(2)(B)(iv)(II)). Because "the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement," the patent holder has the option at this point of filing an infringement action in a federal district court against the ANDA filer. *Id.* (citing 35 U.S.C. § 271(e)(2)). If the patent owner or NDA holder does not do so, the FDA's approval of the ANDA "shall be made effective immediately." 21 U.S.C. § 355(j)(5)(B)(iii). But if the patent owner or NDA holder brings suit within 45 days of receiving notice of the Paragraph IV certification, "'the approval shall be made effective upon the expiration of [a] thirty-month period beginning on the date of the receipt of the notice,' unless the district court rules on the infringement claim within the 30-month period." *Mylan Lab'ys*, 389 F.3d at 1275 (quoting 21 U.S.C. § 355(j)(5)(B)(iii)).

"If the district court issues a ruling during the 30-month . . . period, the ANDA approval date is determined by the decision of the district court, or the appellate court if appealed." *Id.* Multiple possibilities exist. Unsurprisingly, "[i]f before the expiration of [the thirty-month] period the district court decides that the patent is invalid or not infringed . . . , the approval shall be made effective on the date on which the court enters judgment reflecting the decision." 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). Alternatively, if "the district court decides that the patent has been infringed" and "if the judgment of the district court is appealed, the approval shall be made effective on the date on which the court of appeals decides that the patent is invalid or not infringed." *Id.* § 355(j)(5)(B)(iii)(II)(aa)(AA). Finally, if "the district court decides that the patent has been infringed" and "if the judgment of the district court is not appealed or is

affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35." *Id.* § 355(j)(5)(B)(iii)(II)(bb).[1]

If "an applicant who has submitted a [P]aragraph IV certification . . . is sued for patent infringement" and "if a court enters a final decision from which no appeal has been or can be taken . . . that includes a finding that the patent is infringed," FDA regulations require the ANDA applicant to "submit an amendment to change its certification." 21 C.F.R. § 314.94(a)(12)(viii)(A). The applicant can either certify "under paragraph (a)(12)(i)(A)(3) . . . that the patent will expire on a specific date [(i.e., a Paragraph III certification)]" or, "with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (a)(12)(iii) of this section if the applicant amends its ANDA such that the applicant is no longer seeking approval for a method of use claimed by the patent." *Id.* Paragraph (a)(12)(iii), in turn, implements the section-viii-statement escape hatch and permits the ANDA filer to explain "that the [a listed] method-of-use patent does not claim" a use for which the applicant is seeking approval. 21 C.F.R. § 314.94(a)(12)(iii)(A); *see also* 21 U.S.C. § 355(j)(2)(viii). "Once an amendment for the change has been submitted, the ANDA will no longer be considered to contain a [P]aragraph IV certification to the patent." *Id.*

Finally, "[i]n order to encourage [P]aragraph IV challenges, thereby increasing the availability of low-cost generic drugs, the [Food, Drug, and Cosmetic Act] provides that the first company to win FDA approval of an ANDA containing a [P]aragraph IV certification has the right to sell its drug without [generic] competition for 180 days." *Purepac Pharm.*, 354 F.3d at

[1] FDA regulations mirror this statutory language and provide that "[i]f before the expiration of the 30–month period . . . the district court decides that the patent has been infringed, and if the judgment of the district court is not appealed or is affirmed, the . . . ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A)." 21 C.F.R. § 314.107(b)(1)(iv).

879 (quoting 21 U.S.C. § 355(j)(5)(B)(iv)); *Amneal Pharms. LLC v. Food & Drug Admin.*, 285 F. Supp. 3d 328, 334 (D.D.C. 2018) ("To 'compensate [generic] manufacturers for research and development costs as well as the risk of litigation from patent holders,' Congress enacted an incentive for generic drug manufacturers to submit ANDAs and, if necessary, to engage in patent litigation." (quoting *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008))). "The statute and the implementing regulation create this exclusivity period by prohibiting the FDA from approving any other ANDA that contains a [P]aragraph IV challenge to the same patent until 180 days after the first [ANDA filer] markets its drug or 180 days after the first [filer] wins a patent-infringement suit involving that patent, whichever comes first." *Purepac Pharm. Co. v. Thompson*, 354 F.3d at 880 (citing 21 C.F.R. § 314.107(c)(1)). In contrast, the approval of an ANDA with "a section viii statement does not entitle a successful applicant to the 180–day period of exclusivity bestowed on [P]aragraph IV applicants." *Id.*

**B. Factual Background**

Norwich filed its original ANDA for a generic form of rifaximin in December 2019. Dkt. 4-1 at 16. That ANDA contained Paragraph IV certifications for twenty-three listed patents. After receiving notice of Norwich's Paragraph IV certifications, Salix filed a timely patent infringement action in the U.S. District Court for the District of Delaware (the "Delaware District Court"). *See Salix Pharmaceuticals, Ltd. et al v. Norwich Pharmaceuticals, Inc.*, 20-cv-430 (D. Del.) (hereafter "*Norwich I*"). Salix's complaint asserted all twenty-three patents, but during the litigation, the parties narrowed the field of dispute to seven patents by stipulating to the entry of "[a] final judgment of noninfringement . . . with respect to Norwich's current ANDA No. 214369, including the current ANDA Product and any use of the current ANDA Product, concerning each claim of the" remaining sixteen patents. *Norwich I*, Dkt. 180 at 1–2. The

stipulation defined "Norwich's current ANDA No. 214369" and "current ANDA Product" to "include[] any amendments or supplements to the ANDA that do not change the indications of use, the polymorph forms, or the formulation, and include[] any amendments or supplements to the label that are required due to an amendment or supplement to the Xifaxan label." *Id.* at 2 n.1.

The seven disputed patents fell into three categories: (1) drug substance and product patents; (2) method-of-use patents covering the HE indication; and (3) method-of-use patents covering the IBS-D indication. After a four-day bench trial, the Delaware District Court issued an opinion on August 10, 2022 finding that (1) the drug substance and product patents were invalid as obvious, (2) the method-of-use patents covering the HE indication were valid and infringed by Norwich's ANDA, and (3) the method-of-use patents covering the IBS-D indication were invalid as obvious. Dkt. 4-4 at 47.

Prior to issuing its final judgment, the Delaware District Court ordered the parties to "meet and confer and file a joint proposed final judgment." *See Norwich I*, July 28, 2022 Min. Order. In response, the parties presented starkly contrasting views about "whether the Court should determine now if Norwich's ANDA would induce infringement in the future based on hypothetical changes Norwich may make to its ANDA (which [at that time was] still under review and lacks tentative approval)." *Norwich I*, Dkt. 196 at 2. Salix challenged Norwich's proposed final judgment on the ground that it

> would automatically allow the FDA to approve [the pending] ANDA if Norwich were to amend it to carve out the HE indication (i.e., a label that is different from the one litigated by the parties) without any further action by [the Delaware District Court], by limiting the relief under § 271(e)(4)(A) (setting the date of earliest ANDA approval) to only an "ANDA with proposed labeling containing the indication 'reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults."

*Id.* Salix argued that that would be "improper because[,] under § 271(e)(4)(A), the date of approval is tied to the drug product, not an indication." *Id.* Instead, Salix argued, the court's order and judgment should "apply to 'Norwich's ANDA,' period." *Id.* According to Salix's submission, "'Norwich's ANDA' served as the act of infringement under § 271(e)(2)(A) giving rise to jurisdiction, not a particular indication. The parties litigated and the [Delaware District Court] asked the parties to assume that it decided that 'Norwich's ANDA' would induce infringement of the Asserted HE Patents." *Id.*

Unsurprisingly, Norwich took a very different view. It argued:

> Salix's assertion that Norwich's proposed judgment seeks an advisory opinion is erroneous. In fact, the opposite is true. Norwich's proposed judgment is based on only what has been adjudicated by this Court—that the HE indication in Norwich's label induces infringement of the HE patents and that the HE patents are valid. In contrast, by ordering that FDA delay the effective date of approval of Norwich's ANDA regardless of whether the ANDA contains an indication directed to HE, Salix seeks a judgment that deems any label proposed in Norwich's ANDA infringing. Yet, Salix is not entitled to such broad or speculative relief because that issue exceeds the scope of jurisdiction of this Court.
>
> This is especially true where the law permits ANDA applicants to carve out an indication from the drug label. 21 U.S.C. § 355(j)(2)(A)(viii). If Norwich were to carve out the HE indication from its proposed ANDA labeling, then the predicate for delaying the approval of Norwich's ANDA until after the expiration of the asserted HE patent claims under Section 271(e) would no longer exist. Norwich does not ask this Court to enter judgment regarding, or "pre-approve," a proposed "skinny" label for only the IBS-D indication. It asks this Court to reject any proposed judgment that presupposes labeling excluding the HE indication would infringe the asserted HE patent claims[] or [that] precludes Norwich's ability to seek a skinny label.

*Id.* at 5.

After considering the parties' submissions, the Delaware District Court issued an order, which provided, in relevant part, as follows:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the Food and Drug Administration ("FDA") of

> Norwich's ANDA No. 214369 is to be a date not earlier than the date of expiration of the last to expire of the '573, '195, and '397 Patents (currently October 2, 2029) [(the HE method-of-use patents)], plus any regulatory exclusivity to which Plaintiffs are or become entitled.

Dkt. 4-5 at 3. In a memorandum accompanying this order, the Delaware District Court explained that it chose this formulation because:

> [t]he scope of my ruling is that the HE patents are not invalid, and that the HE indication would infringe the HE patents. Norwich's proposed ANDA has the HE indication. I cannot rule on facts that are not before me. That Norwich may seek to carve out the HE indication as permitted by 21 U.S.C. § 355(j)(2)(A)(viii) is immaterial to this analysis. That label is not before me.

Dkt. 4-6 at 3.

Following this decision, Norwich took steps to fill that vacuum. It submitted "a Patent and Labeling Amendment" to its ANDA, in which it withdrew its Paragraph IV certifications regarding the HE method-of-use patents and substituted a section viii statement in their place. Dkt. 51 at 55–57 (A.R. 301–303). Then, the next day, Norwich filed a Rule 60(b) motion in the Delaware District Court, seeking to modify the court's order and final judgment.[2] In particular, Norwich sought "to modify a portion of the [Delaware District Court's] Final Judgement . . . by limiting the order under Section 271(e)(4)(A) that is blocking the approval of Norwich's ANDA until the expiration of the . . . HE Patents directed to hepatic encephalopathy." Dkt. 51 at 23 (A.R. 269). In support of this request, Norwich provided the court with a copy of its amendment and the revised label, and it argued that because the new, proposed label excluded the HE

[2] Under Rule 60(b), a "court may relieve a party . . . from a final judgment, order, or proceeding," due to: (1) "mistake, inadvertence, surprise, or excusable neglect;" (2) "newly discovered evidence" under certain circumstances; (3) fraud . . . , misrepresentation, or misconduct by an opposing party;" (4) a "void" judgment; (5) the satisfaction, release, or discharge of a judgment; or (6) "any other reason that justifies relief." Fed. R. Civ. P. 60(b).

indication, "the predicate for ordering [the] FDA to delay the effective date of the approval of Norwich's ANDA . . . no longer exists." *Id.*

The Delaware District Court was unpersuaded for three reasons. First, that court disagreed that Norwich's decision to carve-out the HE indication, even if the carve-out was done properly, constituted "a significant change in circumstances" sufficient to warrant relief under Rule 60(b)(5). Dkt. 51 at 113–14 (A.R. 359–60). Rather, the court concluded, Norwich's decision to amend it ANDA was "simply a voluntary decision of the trial loser to change course, which is neither unanticipated nor unforeseeable" and therefore outside the ambit of Rule 60(b)(5). *Id.*

Second, the court observed that "[i]t is not a simple matter to determine whether an ANDA applicant has successfully carved out language from a label to turn infringement into non-infringement" and that Norwich "presented no evidence in support of its assertion" that it had properly done so. *Id.* at 115 (A.R. 361). The court also stressed that Rule 60(b) is not an invitation to relitigate issues that were or could have been resolved at trial and that Norwich had failed to present any basis to conclude "that it could not have litigated the carve-out or that it was denied a full and fair opportunity to do so." *Id.* In response to Norwich's contention that Salix had not even "tried to state a claim against the carve out," the court merely observed that it was "unpersuaded that [Salix] [had] some duty . . . to state a claim on something that [Norwich] never raised as an issue before entry of final judgment." *Id.* In short, in the view of the Delaware District Court, Norwich's Rule 60(b) motion amounted to a request for "a second litigation," a door that the court was unprepared to open based on Norwich's minimal showing. *Id.*

Finally, the Delaware District Court noted that Norwich's request was "unprecedented in an ANDA case." *Id.* at 116 (A.R. 362). Against this backdrop, the court wrote: "I am hesitant to be the first, because it seems wrong to me that [Norwich] can litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had started with, and win in a summary proceeding." *Id.*

Both Norwich and Salix have appealed aspects of the Delaware District Court's judgment to the Federal Circuit. Norwich has appealed the court's final judgment "to the extent that it bars the U.S. Food and Drug Administration from approving Norwich's ANDA No. 214369 ('ANDA') prior to the expiration of [the HE indication method-of-use patents] when the ANDA does not contain a Paragraph IV patent certification to any of those patents," Dkt. 4-10 at 2, and, instead, includes a paragraph viii statement. Salix, in turn, has appealed the final judgment to the extent the Delaware District Court found that Salix's IBS-D method-of-use patents and its drug substance and product patents are invalid. *Norwich I*, Dkt. 198 at 1.

After both parties noticed their appeals to the Federal Circuit, the FDA granted "tentative approval" to Norwich's ANDA on June 2, 2023. FDA regulations explain that "[t]entative approval is notification that an NDA or ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved . . . because a court order pursuant to 35 U.S.C. 271(e)(4)(A) orders that the NDA or ANDA may be approved no earlier than the date specified." 21 C.F.R. § 314.3(b). "A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval letter after any necessary additional review of the NDA or ANDA." *Id.*

The FDA explained that it was "unable to grant final approval to [Norwich's] ANDA at this time" for the following reasons:

> [Norwich's] ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Rifaximin Tablets, 550 mg, under this ANDA. . . . Litigation was initiated within the statutory 45-day period against Norwich for the infringement of the '620, '199, '206, '542, '275, '644, '781, '196, '569, '949, '573, '904, '452, '231, '968, '195, '397 and '384 patents in the United States District Court for the District of Delaware . . . . [Norwich] notified the Agency that on August 10, 2022, the court decided, "Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the Food and Drug Administration ("FDA") of Norwich's ANDA No. 214369 is to be a date not earlier than the date of expiration of the last to expire of the '573, '195, and '397 Patents (currently October 2, 2029), plus any regulatory exclusivity to which Plaintiffs are or become entitled. Norwich shall notify the FDA of this judgment within two (2) business days of its entry (with a copy of such notice given simultaneously to Plaintiffs)." [Norwich] further notified the Agency that on May 17, 2023, the court denied Norwich's Rule 60(b) motion to modify the final judgment. Therefore, final approval cannot be granted until October 2, 2029 as specified in the court order.

Dkt. 51 at 119, 121 (A.R. 365, 367). In reaching this conclusion, the FDA acknowledged that Norwich had sought to carve-out the HE indication from its amended ANDA. The agency observed that "with respect to" the '573, '195, and '397 patents, which the Delaware District Court found that Norwich's original ANDA infringed, Norwich's amended ANDA "contains [paragraph viii statements representing that] these are method-of-use patents that do not claim any indication for which you are seeking approval under [its] ANDA." *Id.* at 120–21 (A.R. 367–68); *see also id.* at 123 n.2 (A.R. 369). But, notwithstanding that acknowledgement, the FDA failed to grant final approval to Norwich's amended ANDA.

### C. Procedural History

Disappointed by that decision, Norwich brought this suit on June 6, 2023. Dkt. 1. It alleges that the FDA's decision "refus[ing] to grant Norwich's amened ANDA final approval[,] despite a properly-filed statement under 21 C.F.R. § 314.94(a)(12)(viii)(A) that it is not seeking FDA approval for a patented method of use" was "arbitrary, capricious, and unlawful." *Id.* at 2

(Compl. ¶ 1). It seeks both a declaratory judgment and "an injunction directing [the] FDA to immediately grant Norwich's [a]mended ANDA final approval." *Id.* at 3 (Compl. ¶10). The same day that it initiated the action, Norwich moved for a preliminary injunction. Dkt. 4.

In a joint status report filed on June 12, 2023, the parties urged the Court to consolidate Norwich's motion for a preliminary injunction "with a full consideration of the merits under Rule 65(a)(2) of the Federal Rules of Civil Procedure" in order "to conserve judicial and party resources." Dkt. 8 at 1. That same day, Salix moved to intervene as a defendant, Dkt. 12, and the Court subsequently granted that motion, *see* June 18, 2023 Min. Order. The Court also granted the parties' joint motion to consolidate the pending motion for a preliminary injunction with consideration of the merits of the action and set a schedule for further briefing, *see* June 18, 2023 Min. Order.[3]

Now pending before the Court are Norwich's motion for a preliminary injunction and consolidated motion for judgment on the merits, the FDA's cross-motion for summary judgment, and Salix's cross-motion to dismiss or, in the alternative motion, for summary judgment. *See* Dkt. 4, 37, 54.

[3] About two months later, another generic manufacturer, Teva Pharmaceuticals USA, Inc., moved to intervene, asserting that an order requiring the FDA immediately to grant approval to Norwich's amended ANDA would interfere with Teva's asserted right to a period of 180-days of generic exclusivity. Dkt. 56. After Norwich clarified that it was no longer seeking immediate relief and conceded that, even if Norwich was successful in this case, the FDA would still need to resolve the question of generic exclusivity, if any, in the first instance, *see* Dkt. 58, the Court denied Teva's motion to intervene. The Court left the door open to Teva's intervention, however, should the question of immediate relief reappear in the case. *See* Oct. 6, 2023 Min. Order.

## II. STANDARD OF REVIEW

### A. Federal Rule of Civil Procedure 65

A preliminary injunction "is an extraordinary remedy never awarded as of right," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), but "only when the party seeking the relief, by a clear showing, carries the burden of persuasion," *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). To obtain a preliminary injunction, the movant "must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20.

### B. Federal Rule of Civil Procedure 12(b)(1)

As the party seeking to invoke the Court's jurisdiction, Norwich bears the burden of establishing that it has standing to sue. *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). To survive a Rule 12(b)(1) motion to dismiss for a lack of standing, the plaintiff "must state a plausible claim that [it] has suffered an injury in fact fairly traceable to the actions of the defendant that is likely to be redressed by a favorable decision on the merits." *Humane Soc'y of the U.S. v. Vilsack*, 797 F.3d 4, 8 (D.C. Cir. 2015). "In this posture, the Court must accept the factual allegations of the complaint as true but must nonetheless assess the 'plausibility' of the plaintiff's standing allegations in light of the relevant context and the Court's 'judicial experience and common sense.'" *Teva Pharms. USA, Inc. v. Azar*, 369 F. Supp. 3d 183, 195 (D.D.C. 2019) (quoting *Pub. Citizen, Inc. v. Trump*, 361 F. Supp. 3d 60, 71 (D.D.C. 2019)).

### C. Federal Rule of Civil Procedure 12(b)(6)

A motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6) "tests the legal sufficiency of the complaint." *Browning v. Clinton*, 292 F.3d 235,

242 (D.C. Cir. 2002). In evaluating a Rule 12(b)(6) motion, the Court "must first 'tak[e] note of the elements a plaintiff must plead to state [the] claim' to relief, and then determine whether the plaintiff has pleaded those elements with adequate factual support to 'state a claim to relief that is plausible on its face.'" *Blue v. District of Columbia*, 811 F.3d 14, 20 (D.C. Cir. 2015) (alterations in original) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675, 678 (2009)). A plaintiff may survive a Rule 12(b)(6) motion even if "recovery is . . . unlikely," so long as the facts alleged in the complaint are "enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007). For the purposes of assessing a Rule 12(b)(6) motion, the Court may consider only "the facts contained within the four corners of the complaint, along with any documents attached to or incorporated into the complaint, matters of which the court may take judicial notice, and matters of public record." *Afanasieva v. Wash. Metro. Area Transit Auth.*, 588 F. Supp. 3d 99, 105 (D.D.C. 2022) (quotation marks omitted).

**D. Federal Rule of Civil Procedure 56**

Under Rule 56, summary judgment is available if the movant demonstrates "that there is no genuine dispute as to any material fact and" that, based on the uncontested facts, "the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In the unique context of a case brought under the APA, however, the district court "sit[s] as an appellate tribunal," *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1222–23 (D.C. Cir. 1993), to decide "as a matter of law [whether] the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review," *Coal. for Common Sense in Gov't Procurement v. United States*, 821 F. Supp. 2d 275, 280 (D.D.C. 2011). "In short, it is the role of the administrative agency to 'resolve factual issues' and 'to arrive at a decision that is supported by the administrative record,' while it is the role of the district court 'to determine

whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Amneal Pharms. LLC v. Food & Drug Admin.*, 285 F. Supp. 3d 328, 339 (D.D.C. 2018) (quoting *Hi–Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 18 (D.D.C. 2008)).

## III. ANALYSIS

### A. Standing

Because standing is a threshold issue, the Court addresses it first. *See Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 596 (D.C. Cir. 2015). "To invoke the jurisdiction of the federal courts, a plaintiff must allege (1) a concrete injury (2) caused by the defendant (3) that a favorable judicial decision will redress." *Common Cause v. Biden*, 748 F.3d 1280, 1284 (D.C. Cir. 2014). "Causation, or 'traceability,' examines whether it is substantially probable that the challenged acts of the defendant, not of some absent third party, will cause the particularized injury of the plaintiff." *Fla. Audubon Soc. v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (quotations and citations omitted).

The FDA argues that Norwich lacks standing to sue because the company has not, and will not, suffer any injury caused by the FDA's decision to grant only preliminary approval to the amended ANDA. As the FDA frames the issue, Norwich's "present inability to market rifaximin is traceable to the Delaware [District] Court's Patent Orders and not [the] FDA." Dkt. 40 at 23. In advancing this argument, the FDA acknowledges that Norwich is challenging the FDA's tentative approval decision, but it counters that because the FDA's reasoning for its tentative-approval decision rests solely on the Delaware District Court's final judgment, any injury that Norwich has suffered, or will suffer, is traceable to that judgment and not to any independent action (or inaction) taken by the FDA. *Id.* at 23–24.

The problem with the FDA's argument is that it assumes that it is right on the merits of the question of whether the Delaware District Court's judgment compelled the FDA to postpone the grant of final approval to Norwich's amended ANDA until October 2, 2029. But that is precisely the question that Norwich asks this Court to resolve. The heart of the dispute in this litigation is whether the FDA correctly read the Delaware District Court's order to apply to Norwich's *amended* ANDA. *See, e.g.*, Dkt. 1 at 19 (Compl. ¶ 69) ("[I]t was . . . improper for FDA to refuse to grant final approval to Norwich's Amended ANDA based on the district court's order relating to the HE Patents."); *id.* at 18 (Compl. ¶ 65) ("FDA's decision to not approve Norwich's Amended ANDA contravenes FDA's own regulations, FDA's statements when it issued the proposed and final regulations, and numerous cases discussing the importance of quickly approving generic drug products with section viii statements and carved-out labels."); *id.* at 23 (Compl. ¶ 96) ("As set forth above, FDA improperly decided that it could not grant final approval to Norwich's Amended ANDA based on the decision by the Delaware District Court.").

An admittedly imperfect parallel can be drawn to *Teva Pharmaceuticals, USA, Inc. v. U.S. Food & Drug Administration*, 182 F.3d 1003 (D.C. Cir. 1999). In that case, an ANDA applicant claimed that the FDA's determination that a district court order did not trigger a period of exclusivity for successful ANDA applicants was arbitrary and capricious. *Id.* at 1004. Specifically, the FDA had declined to "recognize the dismissal of a declaratory judgment complaint for patent infringement as a 'court decision'" because the period of exclusivity was only for applicants who had obtained "a 'decision of a court' in a patent or declaratory judgment action 'holding' that the patent is either "invalid or not infringed" and the FDA did not read the district court order had held as such. *Id.* at 1004–05 In reviewing the lower court's resolution of the arbitrary and capricious claim, the D.C. Circuit did not dismiss the case for lack of standing

for the obvious reason that the alleged injury was traceable to the FDA's interpretation (or understanding) of the district court's order. Here, too, this lawsuit challenges only the FDA's interpretation of the Delaware District Court's final judgment.

The cases that the FDA cites involve a very different scenario, in which the plaintiff is not challenging the agency's reading of a court order but the substance of the order itself. In *Cigar Association of America v. U.S. Food & Drug Administration*, 411 F. Supp. 3d 1 (D.D.C. 2019), for example, the plaintiff sought declaratory relief, "not premised on any claimed violation of law by the FDA, or by the FDA's failure to take required action," *id.* at 4, but on the FDA's implementation of a court order (in a different lawsuit) that compelled the agency "to implement the substantial equivalence requirement for all newly deemed products [including cigar and pipe tobacco products] within ten months." *id.* at 3. There, the asserted injury was "entirely a function of a judicial ruling," and, notably, the plaintiffs "effectively concede[d] as much." *Id.* Here, in contrast, the scope of the Delaware District Court Order is both disputed and central to the case. Although a separate action challenging the substance of the Delaware District Court's order is pending before the Federal Circuit, this case raises the distinct claim that the FDA simply misread the court's final judgment. To be sure, there is a noticeable tension between Norwich's argument before the Federal Circuit that the Delaware District Court's judgment sweeps too broadly and its contention here that the FDA erred in reading the final judgment more broadly than warranted. But nothing in the law precludes the company from hedging against any uncertainty about how this Court and the Federal Circuit might read the judgment.

Finally, the FDA argues that, even if Norwich has Article III standing, this Court should decline to exercise jurisdiction "over Norwich's impermissible collateral attack on the patent

orders." Dkt. 40 at 24 (capitalization altered). As the FDA correctly observes, "federal district courts lack the power to void or otherwise alter other federal courts' orders through a collateral attack." *Id.* at 25 (quoting *McNeil v. Brown*, No. 17-2602, 2018 WL 4623057, at *7 (D.D.C. Sept. 26, 2018)). Salix, for its part, frames this argument in slightly different terms, arguing that (1) Norwich is collaterally estopped from challenging the Delaware District Court's final judgment in this action, rather than simply pursuing the pending Federal Circuit appeal or, in the alternative, (2) that principles of comity preclude this Court from "wading into issues pending" before other courts. Dkt. 39 at 16–18. But however framed, the argument fails for the same reason the FDA's challenge to Norwich's standing fails. As clarified beyond any doubt at oral argument, Norwich is not challenging the correctness of the Delaware District Court's final judgment *in this case* and is not asking *this Court* to substitute its views for those of the Delaware District Court or the Federal Circuit. It is merely challenging the FDA's reading of the final judgment entered by the Delaware District Court. *See* Oct. 6, 2023 Hrg. Tr. at 9–10. Whether that argument is meritorious, and whether "principles of comity" might counsel in favor of waiting for further guidance from the Federal Circuit, is beside the point when it comes to the Court's jurisdiction. And when it comes to the merits, the Court has (as explained below) considered whether it would be prudent to wait for the Federal Circuit before resolving this dispute.

**B. Adequate Alternative Remedy**

Defendants also argue that the Court should dismiss Norwich's APA claim because the company has an "adequate alternative remedy" through its appeal to the Federal Circuit and, therefore, does not have a claim under the APA. *See Perry Cap. LLC v. Mnuchin*, 864 F.3d 591, 621 (D.C. Cir. 2017) (holding "the absence of [an adequate alternative] remedy is . . . an element

of the cause of action created by the APA" rather than a jurisdictional question). For reasons similar to those just discussed, the Court is unpersuaded.

The APA "limits judicial review under that statute to agency actions 'for which there is no other adequate remedy in a court.'" *Citizens for Resp. & Ethics in Wash. v. U.S. Dep't of Just.*, 846 F.3d 1235, 1238 (D.C. Cir. 2017) (quoting 5 U.S.C. § 704). This limitation "reflects Congress' judgment that 'the general grant of review in the APA' ought not 'duplicate existing procedures for review of agency action' or 'provide additional judicial remedies in situations where Congress has provided special and adequate review procedures.'" *Id.* at 1244 (quoting *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988)). "Courts must, however, avoid lightly 'construi[ing] [§ 704] to defeat the [APA's] central purpose of providing a broad spectrum of judicial review of agency action.'" *Id.* (alterations in original) (quoting *Bowen*, 487 U.S. at 903).

To determine "whether an alternative remedy is 'adequate' and therefore preclusive of APA review," the Court must "look for 'clear and convincing evidence' of 'legislative intent' to create a special, alternative remedy and thereby bar APA review." *Id.* (quoting *Garcia v. Vilsack*, 563 F.3d 519, 523 (D.C. Cir. 2009)). "Thus, for example, relief will be deemed adequate 'where a statute affords an opportunity for de novo district-court review' of the agency action." *Garcia v. Vilsack*, 563 F.3d 519, 522–23 (D.C. Cir. 2009) (quoting *El Rio Santa Cruz Neighborhood Health Ctr. v. U.S. Dep't of Health & Human Servs.*, 396 F.3d 1265, 1270 (D.C. Cir. 2005). In such cases, "Congress did not intend to permit a litigant challenging an administrative denial . . . to utilize simultaneously both [the review provision] and the APA." *Id.* at 523 (quoting *El Rio Santa Cruz Neighborhood Health Ctr.*, 396 F.3d at 1270).

Defendants maintain that the patent-infringement adjudicatory process, including Norwich's Rule 60(b) motion in the underlying patent litigation and its appeal to the Federal

Circuit, have provided (and are continuing to provide) Norwich with a more than adequate remedial process. In their view, "[i]n enacting [the] Hatch-Waxman [Act], 'Congress plainly contemplated that the affirmative patent infringement action [that follows a Paragraph IV certification]'—rather than administrative action by FDA—would 'resolve any dispute between the patentholder and the [ANDA] applicant and lead to the establishment of the effective date of approval for the [ANDA].'" Dkt. 40 at 28 (quoting *Avadel CNS Pharms., LLC v. Becerra*, 638 F. Supp. 3d 23, 33 (D.D.C. 2022)). And "[b]ecause Norwich seeks relief from the consequences of a judgment in a patent suit," they argue that Norwich's "pending Federal Circuit appeal is more than adequate to displace APA review." *Id.*

Although that argument is not without initial appeal, it once again misunderstands the nature of Norwich's claim in this case: Norwich maintains (at least for purposes of this litigation) (1) that the judgment entered by the Delaware District Court did not address—and did not purport to address—an amended ANDA that was not before the court and (2) that the FDA simply misread that final judgment. Norwich is not arguing that the Delaware District Court was wrong in finding the HE method-of-use patents valid and infringed. *See* Dkt. 4-1 at 17 ("Norwich has not, and does not intend to, appeal the district court's holdings that Norwich's Original ANDA infringes the Asserted HE Patents or that the HE Patents had not been shown invalid."). Nor is it arguing—at least here—that the Delaware District Court erred in denying its Rule 60(b) motion or that this Court should expressly or implicitly modify the Delaware District Court's judgment to add clarity that the judgment itself lacks. Rather, it contends that the judgment itself is clear; that it does not apply to the company's amended ANDA; and that the FDA's interpretation of the final judgment was arbitrary and capricious and contrary to law. *See id.* at 21–22 ("Although FDA apparently believes that it is hamstrung by the district court's

order, FDA's decision to not approve Norwich's Amended ANDA contravenes FDA's own regulations, FDA's statements when it issued the proposed and final regulations, and numerous cases discussing the importance of quickly approving generic drug products with section viii statements and carved-out labels."); Dkt. 49 at 8 ("With the benefit of the Administrative Record and FDA's memorandum to this Court, it is now apparent that FDA took it upon itself to (in FDA's own words) 'interpret' the Delaware Court's May 17 Order to arrive at its incorrect determination that the earlier Section 271(e)(4)(A) Order applies to Norwich's Amended ANDA. There is no basis for FDA's interpretation . . . ."). The Hatch-Waxman Act does not provide ANDA applicants with a cause of action to challenge the FDA's interpretation of a § 271(e)(4)(A) order entered by a district court at the conclusion of patent-infringement case.

The distinction between the relief that a Paragraph-IV-triggered adjudication provides and the relief that Norwich is seeking here can be seen in the difference between this case and *Avadel CNS Pharmaceuticals, LLC v. Becerra*, 638 F. Supp. 3d 23 (D.D.C. 2022). In *Avadel*, an ANDA applicant tried to use the APA to challenge the FDA's instruction that it submit a patent certification for a particular patent. *Id.* at 28. The ANDA applicant maintained that the instruction was arbitrary and capricious because the patent at issue was not infringed by the application. *Id.* The district court declined to consider the merits of the ANDA applicant's APA claim, concluding that the applicant could challenge the patent through a patent infringement action as provided for by the Hatch-Waxman Amendments, which would determine whether the ANDA infringed a valid patent or not and therefore whether a patent certification was needed. *Id.* at 32. In other words, the applicant there had an adequate alternative remedy because its claim was of the very sort that a patent infringement suit triggered by a Paragraph IV certification is intended to resolve. Norwich, in contrast, has already gone through that

Paragraph IV-triggered adjudicatory process, and it has already received a judgment, the substance of which it does not challenge. Instead, it merely alleges that the FDA misapplied that judicial decision—an argument that does not differ in material respects from a claim that the FDA has misapplied a statute or regulation. Most fundamentally, the challenge is not directed at the lawfulness of Delaware District Court's final judgment, which is all that the Federal Circuit can consider on appeal, but rather at the FDA's alleged failure to comprehend what that judgment actually means.

The flaw with Defendants' alternative-adequate-remedy argument can be highlighted by imagining that the Delaware District Court's judgment was crystal clear and that the FDA indisputably misread the judgment; imagine, for example, that the judgment unambiguously carved out the IBS-D indication and that the FDA simply failed to notice that exclusion. Under those circumstances, Norwich would lack any remedy in the patent litigation, and its only remedy would lie under the APA. Yet, the only material distinction between that scenario and this case is the strength of Norwich's claim, and that is a distinction without a difference when it comes to Defendants' threshold argument. The question at this stage of the analysis is not whether Norwich's argument has legs, but only whether it can leave the starting blocks. Because no other adequate remedy exists for the wrong that Norwich seeks to remedy in this case, Defendants' threshold § 704 defense is unavailing.

### C. Arbitrary and Capricious Review

As explained, the gravamen of Norwich's claim is that the FDA's determination that the Delaware District Court's final judgment precluded it from granting final approval to Norwich's amended ANDA prior to October 2, 2029, was "arbitrary, capricious, . . . or otherwise not in accordance with law" and must therefore be set aside. 5 U.S.C. § 706(2)(A). Because the Court

consolidated the hearing on Norwich's motion for a preliminary injunction with the merits at the parties' request, and because the parties' legal and factual arguments have been thoroughly developed, the Court need not pause to consider Norwich's likelihood of success of the merits or any of the other preliminary injunction factors. Instead, the Court will proceed to the ultimate merits of the case.

That inquiry might take one of two forms. First, the Court might consider whether the FDA's reading of the Delaware District Court's final judgment was "arbitrary and capricious." That form of judicial review "is 'fundamentally deferential.'" *Amneal Pharms.*, 285 F. Supp. 3d at 340 (quoting *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012)). This "does not mean . . . that courts must 'simply accept whatever conclusion an agency proffers,'" *id.* (quoting *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2006)); rather, "it is the Court's role to decide whether the agency acted 'within the scope of its lawful authority,' and whether it engaged in 'reasoned decision[-]making,' but not to second guess an agency's reasonable exercise of the authority that Congress gave it," *id.* (quoting *Tripoli Rocketry Ass'n*, 437 F.3d at 77). Second, the Court might consider whether the FDA's reading of the Delaware District Court's final judgment was "contrary to law," just as it might consider whether the agency's reading of an unambiguous statute or regulation is contrary to law. In considering that question, the Court cannot discern any basis to defer to the FDA's reading of the order. The FDA has no unique expertise in reading federal court orders (and certainly no greater expertise than a court), nor is this a case in which one can plausibly argue that *Chevron*'s gap-filling or political-accountability rationales are served. *See* Moss, Executive Branch Legal Interpretation: A Perspective from the Office of Legal Counsel, 52 Admin. L. Rev. 1303, 1328 (Fall 2000) (discussing the twin rationales for *Chevron* deference). For present purposes,

however, it makes little difference which approach the Court takes, since the FDA's reading of the Delaware District Court's final judgment was not only reasonable but was by far the better reading.

The FDA read the Delaware District Court's final judgment to preclude the agency—without limitation—from granting final approval to Norwich's ANDA before October 2, 2029. That is, on the FDA's reading, the judgment does not recognize an exception for the IBS-D indication (or any other non-HE indication) and, instead, applies to the ANDA without exception. The FDA explained the basis for this conclusion in two documents. The first is a letter that the FDA sent to Norwich, dated June 2, 2023. That letter explained that the FDA was "unable to grant final approval to [Norwich's] ANDA at this time because" the Delaware District Court "ordered that the effective date of *any* final approval by the Food and Drug Administration ("FDA") of Norwich's *ANDA No. 214369* is to be a date not earlier than the date of expiration of the last to expire of the '573, '195, and '397 Patents (currently October 2, 2029), plus any regulatory exclusivity to which Plaintiffs are or become entitled." Dkt. 51 at 119, 121 (A.R. 365, 367) (emphasis added). Norwich does not dispute that, even as amended, the ANDA at issue is "ANDA No. 214369." Nor was the FDA unaware of the Delaware District Court's decision denying Norwich's Rule 60(b) motion. It added: Norwich "notified the Agency that on May 17, 2023, the [Delaware District Court] denied Norwich's Rule 60(b) motion to modify the final judgment. Therefore, final approval cannot be granted until October 2, 2029 as specified in the court order." *Id.* at 121 (A.R. 365).

The second document in which the FDA explained its tentative-approval decision is a [redacted] explains that:

> Norwich's ANDA is eligible for only a Tentative Approval based on the 271(e)(4)(A) judgment [redacted] we interpret the May 17 order refusing to modify the judgment to say that the prior [redacted] still stands and applies to Norwich's post-amendment ANDA.

[redacted] (A.R. 374); Dkt. 40 at 20, 24.

As a result, the basis for the FDA's decision is clear: in the agency's view, the Delaware District Court's final judgment dictated that the earliest date that the FDA could grant final approval to ANDA No. 214369, regardless of whether the ANDA had been amended to carve-out the HE indication, was October 2, 2029. Dkt. 40 at 19–20; Dkt 4-1 at 21; Dkt. 39 at 9–10. Norwich does not dispute that the basis for the FDA's decision is adequately explained and, instead, argues that the agency's decision is both unreasonable and contrary to law because it "contravenes FDA's own regulations, FDA's statements when it issued the proposed and final regulations, and numerous cases discussing the importance of quickly approving generic drug products with section viii statements and carved-out labels." Dkt. 4-1 at 22.

At this point, the Court must return to Norwich's concession—a concession that is necessary to avoid interjecting this Court in a matter appropriately left to the Federal Circuit—that this case does not challenge the lawfulness of the Delaware District Court's final judgment and, certainly, does not posit that the FDA acted unreasonably or in contravention of law by adhering to a district court order that, in Norwich's view, misunderstood the governing FDA regulations and the "cases discussing the importance of quickly approving generic drug products with section viii statements and carved-out labels." *Id.* At oral argument on the pending motions, Norwich unequivocally disavowed that it was making any such argument, *see* Oct. 6,

2023 Hrg. Tr. at 9–10, and, instead, explained that it merely contends "that the best construction of [the Delaware District Court's] order is that [the court] wasn't saying anything at all about an amended ANDA." *Id.* The reasonableness (and accuracy) of the FDA's reading of that order might, of course, be informed by the surrounding statutory and regulatory environment, but, in the end, all that matters for present purposes is how that order is best understood.

In considering that question, the Court starts with the plain text of the Delaware District Court's final judgment. Paragraph 5 of that judgment provides as follows:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the Food and Drug Administration ("FDA") of Norwich's ANDA No. 214369 is to be a date not earlier than the date of expiration of the last to expire of the '573, '195, and '397 Patents (currently October 2, 2029) [(the HE method-of-use patents)], plus any regulatory exclusivity to which Plaintiffs are or become entitled.

Dkt. 4-5 at 3. Norwich's ANDA, even as amended, is still ANDA No. 214369. *Id.* As a result, the FDA's determination tracks the most straightforward reading of the final judgment—the FDA may not grant "final approval" to "Norwich's ANDA No. 214369" before October 2, 2029.

That plain-language reading of the final judgment is reinforced, moreover, by the extensive briefing and argument that came before and after its entry. Prior to issuing its judgment, the Delaware District Court directed the parties to "meet and confer and file a joint proposed final judgment." *See Norwich I*, July 28, 2022 Min. Order. In a letter responsive to that directive, the parties presented their views about whether the Court's judgment should restrict the effective date of approval of Norwich's ANDA only with respect to the HE method-of-use patents and corresponding labeling or with respect to the ANDA more generally, irrespective of any amendment Norwich might submit to the FDA limiting the labeling to the IBS-D indication. Those views were starkly conflicting: Salix asked that the final judgment "apply to 'Norwich's ANDA,' period." *Norwich I*, Dkt. 196 at 2. Norwich, in contrast, argued

that such an order would be overly "broad or speculative" and asked, instead, that the Delaware District Court "reject any proposed judgment that presupposes labeling excluding the HE indication would infringe the asserted HE patent claims, or precludes Norwich's ability to seek a skinny label." *Id.* at 5. Faced with these competing views, the Delaware District Court decided to phrase the final judgment as it did—using broad language with no apparent exemption for a future "skinny label."

To be sure, the Delaware District Court explained in a memorandum accompanying its final judgment that the possibility that "Norwich may seek to carve out the HE indication as permitted by 21 U.S.C. § 355(j)(2)(A)(viii) [was] immaterial to [its] analysis" because such a label was not before the court. Dkt. 4-6 at 3. In Norwich's view, this shows that the court did not intend that its final judgment would foreclose the FDA from approving an amended ANDA that carved-out the HE indication. Had the story ended there, Norwich would have been on stronger footing in challenging the reasonableness of the FDA's interpretation of the final judgment. But it did not end there.

After the Delaware District Court entered its judgment, Norwich amended its ANDA to carve-out the HE indication and then moved to amend the court's judgment to clarify that the judgment did not apply to the amended label. Dkt. 51 at 23 (A.R. 269). Specifically, Norwich asked the court to adopt an amended judgment that would have provided as follows:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the Food and Drug Administration ("FDA") of Norwich's ANDA No. 214369 is to be a date not earlier than the date of expiration of the last to expire of the '573, '195, and '397 Patents (currently October 2, 2029), plus any regulatory exclusivity to which Plaintiffs are or become entitled, *to the extent Norwich's ANDA No. 214369 maintains Paragraph IV certifications pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) stating that the '573, '195, and '397 patents are invalid or will not be infringed by the manufacture, use, or sale of the product specified in Norwich's ANDA.*

*Id.* at 48 (A.R. 294) (emphasis added to reflect proposed revision). The Delaware District Court denied that motion—not because the proposed amendment was unnecessary, but because the court thought it "wrong . . . that [Norwich] can litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had started with, and win in a summary proceeding." Dkt. 4-9 at 6.

Given this history, it is a stretch for Norwich to argue that the final judgment is best read *implicitly* to include the qualifying language that the court *explicitly* declined to include—twice. *Cf. Cigar Ass'n of Am.*, 411 F. Supp. 3d at 4 (concluding that it was implausible to read a court order as exempting cigar and loose tobacco products when "the court's order vacating the [FDA's] Guidance not only notes that the FDA's Guidance applies to cigars," but "declares broadly that 'the August 2017 Guidance must be vacated,'" and "when [p]laintiffs sought clarification from the . . . court as to the breadth of its rulings, that court made clear that its remedial order applies to cigars and pipe tobacco"). Norwich's principal answer to this difficulty merely posits that federal courts, like federal agencies, should be afforded a presumption of regularity, *cf. Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971)), and that reading the final judgment to preclude Norwich from amending its ANDA to exclude labeling for the HE method of use would run afoul of the FDA's governing regulations and the policy favoring the prompt approval of non-infringing generic alternatives to pricier branded drugs. Dkt. 4-1 at 22.

For support, Norwich points to 21 C.F.R. § 314.94(a)(12)(viii)(A), which provides as follows:

> An applicant who has submitted a paragraph IV certification and is sued for patent infringement *must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken*, or signs and enters a settlement order or consent decree in the action that includes

> a finding that the patent is infringed, unless the final decision, settlement order, or consent decree also finds the patent to be invalid. In its amendment, the applicant must certify under paragraph (a)(12)(i)(A)(3) of this section that the patent will expire on a specific date *or, with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (a)(12)(iii)* of this section if the applicant amends its ANDA such that the applicant is no longer seeking approval for a method of use claimed by the patent. *Once an amendment for the change has been submitted, the ANDA will no longer be considered to contain a paragraph IV certification to the patent.* If a final judgment finds the patent to be invalid and infringed, an amended certification is not required.

21 C.F.R. § 314.94(a)(12)(viii)(A) (emphasis added). According to Norwich, it did just what this regulation contemplates: after the Delaware District Court entered a final judgment finding that its ANDA infringed Salix's HE method-of-use patents, Norwich amended the ANDA under paragraph (a)(12)(iii) to include a section viii statement excluding the infringing method of use. It thereby limited the scope of its amended ANDA to those indications covered exclusively by the invalid or non-infringing patents and removed any and all Paragraph IV certifications from the ANDA. Dkt. 4-1 at 22. Norwich maintains that because its ANDA no longer contains a Paragraph IV certification and contains only a section viii statement, its "ANDA may be approved . . . immediately," 21 C.F.R. § 314.107(b)(1)(ii), like any other ANDA that contains a section viii statement (rather than a Paragraph IV certification). *See also* 81 Fed. Reg. 69580, 69624 (Oct. 6, 2016) (explaining that the current version of 21 C.F.R. § 314.94 "clarif[ies] that if a[n] . . . ANDA applicant submits a statement . . . explaining that a method-of-use patent does not claim an indication or other condition of use for which the applicant is seeking approval and submits proposed labeling that appropriately carves out information related to the patented method of use, then the . . . ANDA may be eligible for immediate approval").

As explained above, however, Norwich does not—and cannot—argue in this case that the Delaware District Court erred. Instead, it is left to argue that the law is so clear, and that the

final judgment is so unclear, that the only path forward is to construe the final judgment in the manner that Norwich proposed to the Delaware District Court and that court declined to embrace. Although Norwich raises a substantial argument regarding the meaning of § 314.94(a)(12)(viii)(A), the Court is unpersuaded that the law is as clear, or that the final judgment is as unclear, as Norwich posits.

To start, 21 C.F.R. § 314.94(a)(12)(viii)(A) does not stand alone. Among other relevant provisions, 21 U.S.C. § 355(j)(5)(B)(iii)(II) mandates that the FDA approve an (otherwise sufficient) ANDA with a Paragraph IV certification that is the subject of patent litigation as follows:

> [I]f before the expiration of [the thirty-month stay] the district court decides that the patent has been infringed—
>
> (aa) if the judgment of the district court is appealed, the approval shall be made effective on—
>
> (AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or
>
> (BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or
>
> (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35.

21 U.S.C. § 355(j)(5)(B)(iii)(II). Section 271(e)(4)(A) of Title 35, in turn, requires a district court that has found that a Paragraph IV certification constituted an act of infringement of a valid patent to "order the effective date of *any* approval of *the drug . . . involved in the infringement* to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A) (emphasis added); *see also Vanda Pharm. Inc. v. West-*

*Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1139 (Fed. Cir. 2018) ("[T]he FDA is entitled not to set an approval date prior to the expiration of a patent that has been found to be infringed under § 271(e)(4)(A) and not invalid in a Hatch-Waxman case."); *In re Omeprazole Pat. Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) ("[I]f the FDA has not approved the ANDA before the district court determines that the patent has been infringed, the FDA may not approve the ANDA until the effective date specified by the district court under section 271(e)(4)(A).").

How this statutory scheme interacts with the regulatory path to approval following a finding of infringement raises difficult questions, which have occupied the Federal Circuit and lower courts. Although not directly on point, *Ferring B.V. v. Watson Laboratories, Inc.-Fla.*, 764 F.3d 1382 (Fed. Cir. 2014), is instructive. In that case, a generic manufacturer submitted an ANDA that contained a Paragraph IV certification. The patent owner sued the ANDA filer, and the district court found that the ANDA "was silent with respect to [a key issue]" and thus "permitted [the generic manufacturer] to violate the patent." *Id.* at 1386. During trial, however, the applicant "agreed to amend its ANDA specification to include [an important] restriction," leading the district court to find that the generic manufacturer's "proposed amendment would be outside the scope" of the patent. *Id.* Then, after trial, the generic manufacturer amended its ANDA in the relevant respect, the FDA approved the amendment, and the district court subsequently "concluded that the [amended] ANDA did not infringe the patents-in-suit." *Id* at 1387. Ultimately, the district court found that the ANDA, as originally submitted, infringed the patent but that, by amending its ANDA, the generic manufacturer mooted the plaintiff's complaint. *Id.*

On appeal, the patent holder argued that 35 U.S.C. § 271(e)(4)(A) requires "that once a section 271(e)(2) infringement is found based on the ANDA as first submitted, the district court

*must* order a change in the effective date of the ANDA." *Id.* at 1389 (emphasis in original). The Federal Circuit, however, rejected this bright-line rule and, instead, held that a "district court *may* reconsider its own finding of infringement in light of an amended ANDA or other information." *Id.* at 1391 (emphasis added). The court explained, "[w]e do not suggest that a district court must always consider any ANDA amendment;" rather, "[a]llowing an amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder." *Id.* Applying that abuse-of-discretion standard, the Federal Circuit affirmed the district court's decision to consider the ANDA that was amended *after trial*. In the view of the Federal Circuit, there was little prejudice to the brand-name drug company in considering the amended ANDA because, "even at trial the district court made clear that it was inclined to allow an amendment by [the ANDA applicant] clarifying the dissolution rate of its product, and the district court judge discussed the language of the amendment on the record." *Id.*

Other courts, however, have declined to grant relief under Rule 60(b) based on post-trial amendments to ANDAs that were found at trial to infringe listed patents. In *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, No. 14-1119, 2019 WL 3574249 (D. Del. Aug. 6, 2019), for example, the district court declined to vacate a finding of infringement pursuant to Rule 60(b) based on a post-trial amendment to the defendant's ANDA. In reaching that conclusion, the court distinguished *Ferring* on four grounds. Unlike in *Ferring*: (1) the court's "finding of infringement was not based solely on the ANDA, but also on actual testing of [the] generic product;" (2) "there was no discussion at the trial . . . suggesting that [the defendant] would or should amend its ANDA to moot the issue of infringement;" (3) the plaintiff was likely to suffer prejudice due to the post-amendment amendment, including the cost of further discovery and factfinding regarding the doctrine of equivalents and the risk that the parties would seek to raise

new arguments based on the amendments; and (4) principles of fairness weighed against permitting the defendant "to engage in a do-over, after . . . learn[ing] of the weaknesses in its legal theory." *Id.* at *7–*8. Similarly, in *Allergan, Inc. v. Sandoz Inc.*, No. 09-97, 2013 WL 6253669 (E.D. Tex. Dec. 3, 2013), the district court held that the defendant's "request for a ruling of non-infringement based on the changed ANDA [was] tantamount to seeking summary judgment premised on new allegations that only came to exist after the final judgment was rendered and affirmed." *Id.* at *3. In the court's view, that effort ran afoul of the principle that "a party may not use a Rule 60(b) motion as an occasion to relitigate a case." *Id.* (cleaned-up).

To be sure, the relief that Norwich sought before the Delaware District Court is not on all fours with any of these cases. But many of the same principles apply, and much of the analysis in these decisions mirrors the analysis in the Delaware District Court's decision rejecting Norwich's Rule 60(b) motion. Common sense, moreover, at least arguably suggests that this is not a one-size-fits all question, in which district courts are empowered only to specify an approval date with respect to the infringing methods-of-use and must, invariably, carve out from their judgments any future, amended ANDAs that are limited in scope to those methods-of-use that were not found to be infringing at trial. As Salix notes, that approach might—at least at time—unfairly prejudice patent holders, who focus their litigation strategy and discovery on the ANDA *as it existed at trial*, and might—at least at times—invite multiple rounds of litigation, as patent holders seek to respond to post-trial ANDA amendments by raising arguments that were either left on the cutting-room floor or unapparent prior to the amendment.

The Court expresses no view on the ultimate merits of these questions—and, certainly, takes no view on how these principles might apply to the Delaware District Court's Rule 60(b) decision. Those questions are not before this Court, and they are the sole domain of the Federal

Circuit. All that matters for present purposes is that Norwich has failed to show that the law is so clear that the FDA should have stretched to read the Delaware District Court's final judgment and Rule 60(b) decision in a manner that ignores their plain terms. That proposition is unsustainable, as is Norwich's ultimate contention that the FDA erred as a matter of reasoned-decision-making and law in reading those documents to leave the agency free to approve the company's amended ANDA prior to October 2, 2029.

**D. Summary Judgment**

The Court pauses to consider one final question. Although the Court is persuaded that the Delaware District Court unambiguously directed that the FDA wait until October 2, 2029 to approve ANDA No. 214369 (including any amendment to that ANDA), the direct appeal of the Delaware District Court's judgment is pending before the Federal Circuit, and the Federal Circuit's decision in that appeal might possibly shed additional light on the best reading of the district court's judgment and the surrounding legal principles. For that reason, the Court has considered whether it should simply deny Norwich's motion for a preliminary injunction but wait for any relevant guidance from the Federal Circuit before resolving the parties' cross-motions for summary judgment. For four reasons, however, the Court concludes that there is no reason to postpone the resolution of the pending cross-motions.

First, Norwich and the FDA agreed to consolidate the hearing on Norwich's motion for a preliminary injunction with the merits "[i]n order to conserve judicial and party resources," Dkt. 8 at 1, and they are entitled to the benefit of that streamlined procedure. Second, Norwich has not asked that the Court wait for a decision from the Federal Circuit, nor has it filed an "affidavit or declaration" pursuant to Rule 56(d) showing that it "it cannot present facts essential to justify its opposition." Third, and most importantly, if the Federal Circuit issues a decision that casts

doubt on the FDA's reading of the Delaware District Court's final judgment, Norwich's remedy is not to return to this Court for further consideration but, rather, to ask the FDA to reconsider its decision. Counsel for Norwich conceded as much at oral argument, acknowledging that "there's never a time when you can't" ask the FDA to reconsider and that the only reason it has not done so to date is because the company "didn't think it would be fruitful." *See* Transcript, Oct. 6, 2023 Hrg. Tr. at 17. The Court put the question even more directly to counsel for the FDA, asking what would happen if the Federal Circuit were to read the final judgment in the manner that Norwich urges in this case (and not as Norwich urges in the direct appeal). He responded: "then Norwich would notify [the] FDA of the authoritative construction of the order." *Id.* at 30–31. The availability of reconsideration before the agency resolves the matter, since basic tenets of administrative law require agencies, whenever possible, to consider and opine on new arguments before those arguments are raised in APA litigation, and, here, the parties agree that Norwich will have the opportunity to bring any relevant developments to the attention of the agency in the first instances. Finally, the prospect that the Federal Circuit will construe the Delaware District Court's final judgment in the manner that Norwich urges in this case is, at best, remote. For the reasons explained above, that reading is exceedingly difficult to square with the text of the final judgment and with the court's Rule 60(b) decision, and, notably, no party—not even Norwich—is urging the Federal Circuit to adopt that unconventional reading.

## CONCLUSION

For the foregoing reasons, the Court will **DENY** Plaintiff's motion for a preliminary injunction, Dkt. 4, will **GRANT** the FDA and Salix's cross-motions for summary judgment, Dkt. 37, Dkt. 54.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: November 1, 2023